



## SAFETY DATA SHEET

### SECTION 1 – IDENTIFICATION OF THE PRODUCT & THE COMPANY

- a) **Product Name** : Etomidate Injection, USP, 2 mg/mL
- b) **Common/Trade Name** : Etomidate Injection, USP, 2 mg/mL
- c) **Chemical Names** : R)-(+)-ethyl-1-(1-phenylethyl)-1H-imidazole-5-carboxylate
- d) **Product Use** : Sedative-hypnotic
- e) **Product Type** : Regulated Prescription Drug
- f) **Container Information** : Vial
- g) **Manufacturers Name & Address** : **Gland Pharma Limited**  
: Hyderabad-  
: Telangana, India
- h) **Telephone Number for Info** : +91-40-30510999

### SECTION 2 – HAZARDS IDENTIFICATION

**GHS-Classification** : Not classified as hazardous



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### SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
Etomidate	2 mg/mL	33125-97-2	N/A
Propylene glycol	0.35 mL	57-55-6	N/A
Water	q.s. for mL	7732-18-5	N/A

### SECTION 4 – FIRST AID MEASURES

- Skin Contact** : Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
- Eye Contact** : Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
- Inhalation** : Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
- Ingestion** : Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
- Notes to Physician** : See patient package insert in shipping carton for complete information.

### SECTION 5 – FIRE FIGHTING MEASURES

- a) Extinguishing Media** : As with any fire, use extinguishing media appropriate for primary cause of fire.
- b) Protection during Fire Fighting** : No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self-contained breathing apparatus



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### SECTION 6 – ACCIDENTAL RELEASE MEASURES

- Personal Precautions** : Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure
- Environmental Precautions** : Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release
- Clean Up Methods** : Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

### SECTION 7 – HANDLING AND STORAGE

- General Handling** : Gloves mask and goggles are recommended during handling.
- Storage Conditions** : Protect from light. Store at 20°-25°C (68°-77°F)  
(See USP controlled room temperature).

### SECTION 8 – EXPOSURE CONTROLS/ PERSONAL PROTECTION

#### (a) Exposure Limits

Compound	Exposure Limit
Etomidate	OEB 4 (control exposure to the range of 1ug/m <sup>3</sup> to <10ug/m <sup>3</sup> )
Propylene Glycol	AIHA WEEL 10 mg/m <sup>3</sup> 8 hr TWA

#### (b) Engineering Controls

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section



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### Individual Protection Measures

Respirators	:	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)
Skin	:	Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
Eyes	:	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

### SECTION 09 – PHYSICAL AND CHEMICAL PROPERTIES

a)	<b>Appearance/Description</b>	:	A clear, colorless solution
b)	<b>Odor</b>	:	No data available
c)	<b>Odor Threshold</b>	:	No data available
d)	<b>pH</b>	:	4.0-7.0
e)	<b>Melting Point:</b>	:	Not available
f)	<b>Initial Boiling Point:</b>	:	Not available
g)	<b>Flash Point</b>	:	Not available
h)	<b>Upper Lower Flammability or Explosion Limits</b>	:	Not available
i)	<b>Relative Density</b>	:	Not available
j)	<b>Solubility(ies)</b>	:	In soluble in water, Freely soluble in alcohol and in methylene chloride.
k)	<b>Partition Coefficient: n-octanol/water</b>	:	Not available
l)	<b>Viscosity</b>	:	Not available



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### SECTION 10 – STABILITY AND REACTIVITY

a)	<b>Reactivity</b>	Not determined
b)	<b>Chemical Stability</b>	Stable under normal conditions of use.
c)	<b>Possibility of Hazardous Reactions</b>	Not determined
d)	<b>Conditions to Avoid</b>	Fine particles (such as dust and mists) may fuel fires/explosions
e)	<b>Incompatible Materials</b>	As a precautionary measure, keep away from strong oxidizers
f)	<b>Hazardous Decomposition Products</b>	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides and nitrogen oxides .

### SECTION 11 – TOXICOLOGICAL INFORMATION

a)	<b>Likely Routes of Exposure</b>	Ingestion, inhalation, skin and eyes.
b)	<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	Overdosage may occur from too rapid or repeated injections. Too rapid injection may be followed by a fall in blood pressure. No adverse cardiovascular or respiratory effects attributable to etomidate overdose have been reported
c)	<b>Delayed and immediate effects and also chronic effects from short and long term exposure</b>	<b>Short Term Exposure:</b> Active ingredient may be harmful if swallowed. <b>Long Term Exposure :</b> Repeat-dose studies in animals have shown a potential to cause adverse effects on the Developing fetus.



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Ingredient (s)	Percent	Test Type	Route of Administration	Value	Units	Species
Etomidate	100	LD50	Intravenous	20.4, 14.8 29.5	mg/kg mg/kg	Rat Mouse
Propylene Glycol	100	LD50	Intravenous Intravenous	6423-6800 6630-8000	mg/kg mg/kg	Rat Mouse

### SECTION 12 – ECOLOGICAL INFORMATION

a)	<b>Ecotoxicity</b>	Not determined for product LC50(96 hr) = 0.48 mg/L in Bluegill ( <i>Lepomis macrochirus</i> ) for etomidate LC50(96 hr) = 51,600 mg/L in rainbow trout for propylene glycol LC50(48 hr) = 34,400 - 43,500 mg/L in <i>Daphnia magna</i> for propylene glycol EC50(14 day) = 19,000 mg/L in algae for propylene glycol
b)	<b>Persistence and, degradability</b>	Not determined for product. Propylene glycol was reported to be 100% biodegradable after 24-hours in activated sludge.
c)	<b>Bioaccumulative potential</b>	Not available.
d)	<b>Mobility in soil</b>	Not available
e)	<b>Other Adverse Effects</b>	Not available

### SECTION 13 – DISPOSAL CONSIDERATIONS

**Waste Disposal:** Disposal should be performed in accordance with the federal, state or local regulatory requirements.



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### SECTION 14 – TRANSPORTATION INFORMATION

Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

### SECTION 15 – REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible Gland usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

**U.S. Regulations:**

TSCA: Not available

CERCLA: Not available

SARA 302: Not available

SARA 313: Not available

### SECTION 16 – OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.



## SAFETY DATA SHEET

**Glossary:** This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMDG	International Maritime Dangerous Goods
LEL	Lower Explosive Limit
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit